I. Rejection of Claim 2 under 35 U.S.C. §112, 2nd paragraph

The Examiner has rejected claim 2 under 35 U.S.C. §112, 2nd paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Specifically the Examiner suggests that the phrase "middle molecular weight molecules" is indefinite and that one having skill in the art would have trouble ascertaining the middle molecular weight molecules to which the claim was referring.

Claim 2 has been amended as supported in the specification at page 6, lines 20-29, to clarify that the middle weight molecular molecules are uremic toxins. Uremic toxins are defined in the specification as solutes that are normally excreted by healthy kidneys; accumulate progressively during the development of renal failure; and inhibit physiological and biochemical functions thus contributing to symptoms comprising Uremic Syndrome. A person of skill in the art would have no trouble ascertaining which middle molecular weight molecules are referenced in claim 2 as amended. No new matter was added by this amendment.

Withdrawal of the rejections under 35 U.S.C. § 112, second paragraph, is respectfully requested.

II. Rejection of Claims 1-4 under 35 U.S.C. § 103

The Examiner rejected claims 1-4 under 35 U.S.C. § 103 as being unpatentable over Yatsidis et al. (1979) in view of Prakash et al.(1995) and further in view of Goldenhersh et al. Applicants disagree with the Examiner's suggestion.

The Examiner suggests that because the claimed ingredients were known in the art for treating uremia separately, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have combined the ingredients for their known benefit to treat uremia. Further, the Examiner suggests that one having ordinary skill in the art would have been motivated to microencapsulate the composition to result in a lesser quantity of absorbents being used. Applicants respectfully traverse this rejection.

MPEP § 2143 is quite clear; to establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art to modify the reference or combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art references when

combined must teach or suggest all the claim limitations. The cited prior art combination fails to meet these basic criteria.

At the outset it is respectfully pointed out that claim 1 has been amended to incorporate a gut clearance rate of urea of 5.6 ml. per minute by the composition as supported in the specification at page 11, lines 16-17. No new matter has been added by this amendment.

The composition of the instant invention alleviates the symptoms of uremia using a microencapsulated or enteric coated mixture of: (1) sorbents with specific adsorption affinities for uremic toxins wherein the sorbents possess a gut clearance rate for urea of at least 5.6 ml/minute; and (2) a bacterial source which metabolizes urea and ammonia.

As acknowledged by the Examiner, Yatzidis teaches the use of locust bean gum by itself to absorb uremic substances. Yatzidis does not teach the combination of locust bean gum with a bacterium. Prakash et al. teach the use of a microencapsulated *E.coli* strain (DH5). Prakash et al. do not teach the combination of a sorbent with the DH5. Goldenhersh et al. teach that adsorption competition interferes with the adsorption of creatine on activated carbon. Goldenhersh et al. do not teach the combination of the carbon or other sorbents with a bacterium.

None of the references provide any teaching or suggestion of coupling a bacterium with sorbents in a microencapsulated coating to treat uremia.

Further, none of the cited references provide any teaching or suggestion of a method for alleviating the uremia by a composition which is based upon a bacterial source and sorbents with a required minimum gut clearance rate for urea. Thus, even assuming *arguendo*, that some motivation to combine the references existed, the combination of references fails to teach or suggest all of the claim 1 limitations.

Thus, since the basic criteria set forth for establishing a *prima facie* case of obviousness are not met by the cited references, this combination of prior art cannot render obvious the instant claimed invention.

Withdrawal of this rejection under 35 U.S.C. § 103(a) is therefore respectfully requested.

III. Conclusion

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with Markings to Show Changes Made".

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Claims 1 and 2 have been amended as follows:

1. (amended) A microencapsulated or enteric coated composition comprising:

(a) a mixture of sorbents with specific adsorption affinities for uremic toxins wherein the sorbents possess a gut clearance rate for urea of at least 5.6 ml/minute; and

(b) a bacterial source which metabolizes urea and ammonia.

2. (amended) The composition of claim 1 wherein sorbents of the mixture have specific adsorption affinities for ammonia, urea, creatinine, phenols, indoles, and middle weight molecules wherein the middle weight molecules are uremic toxins.